

North American Pharmacal, Inc.

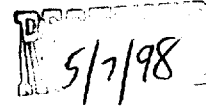
17 High Street

Norwalk, CT 06851

203 866 7664

203 838 4015

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May 4, 1998

Via UPS Next Day Air

Dr. Elizabeth Yetley

Office of Special Nutritionals (HFS-450)

Food and Drug Administration

200 C Street, S.W.

Washington, D.C.

20204

Re: Fulfillment of Reporting Obligation

Under 21 U.S.C. #343(r) and 21 CFR # 101.93

Dear Dr. Yetley:

North American Pharmacal, Inc.¹, in accordance with 21 U.S.C. #343(r) and 21 CFR # 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. North American Pharmacal retains scientific documentation supporting the statements.

Supplement Brand Name

ARA 6 Larch Arabinogalactan

Supplement Ingredients

Arabinogalactan (from Larix occidentalis)

Text of Statements of Nutritional Support

"Larch AG enhanced NK cytotoxicity and supports the normal release of "cytokines" (immune hormones), interferon gamma, tumor necrosis factor alpha, interleukin-1 beta (IL-1 beta) and IL-

1. The address of North American Pharmacal, Inc. is 17 High Street, Norwalk, CT 06851

6.”

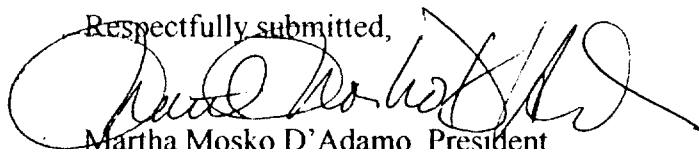
“Ara-6 is also an excellent source of dietary fiber and has been shown to increase the production of short-chain fatty acids (SCFA), principally butyrate.”

“Because of its ability to increase colonic butyrate and colonic ammonia concentrations, arabinogalactan may be a preferable form of fiber.”

“Butyrate has a particularly important role in maintaining colon health.”

In accordance with 21 USC # 343(r)(6) and 21 CFR # 101.93(c), each of the above statements of nutritional support will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **“These statements have not been evaluated by the Food and Drug administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”**

Respectfully submitted,

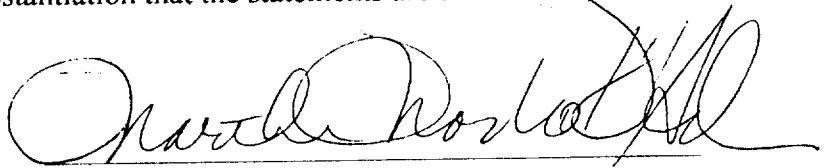
A handwritten signature in black ink, appearing to read 'Martha Mosko D'Adamo', written over a horizontal line.

Martha Mosko D'Adamo, President
North American Pharmacal, Inc.

CERTIFICATION

I, Martha D'Adamo, President of North American Pharmacal, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate, and that North American Pharmacal, Inc. has substantiation that the statements are truthful and not misleading.

Executed on: 5/5/98

A handwritten signature in cursive script, appearing to read 'Martha D'Adamo', written over a horizontal line.

Martha D'Adamo